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(72) Inventor(s)  
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U1S S1037

(56) Documents Cited  
WO 92/22259 A1 WO 91/11965 A1 WO 90/04953 A1  
US 5019083 A US 4248232 A

(58) Field of Search  
UK CL (Edition M ) A5R RAP RAT  
INT CL<sup>5</sup> A61B 19/00 , A61F 2/46  
ONLINE DATABASES: WPI,MEDLINE

(57) A method of securing a prosthesis to a bone includes inserting cement into a cavity formed in the bone, locating the prosthesis in the cemented cavity and, before the cement sets, applying ultrasound to the cement through the prosthesis at a frequency and for a time to substantially eliminate folds and inclusions in the cement. The ultrasonic frequency may be c. 20KHz. Alternatively, a cemented prosthesis may be removed by applying ultrasound thereto firstly at a frequency to cause fatigue fracture of the cement-bone and cement-prosthesis bonds, then at a frequency to cause cavitation in the interface and finally at a frequency to cause thermal softening of the cement. The ultrasound apparatus used may include a magnetostriction transducer 20 connected to a conductive body 10 which has adjustable jaws 12 for gripping the prosthesis 4, and means for controlling the resonant frequency of the transducer.



**The claims were filed later than the filing date within the period prescribed by Rule 25(1) of the Patents Rules 1990.**

CLAIMS:

1. A method for securing a prosthesis to a bone including the steps of  
forming a cavity in a bone,  
5 inserting cement into said cavity,  
locating a prosthesis in the cemented cavity and  
before the cement sets,  
applying ultrasound to the cement through the  
prosthesis at a frequency and for a time to substantially  
10 eliminate folds and inclusions in the cement.
2. A method as claimed in claim 1 wherein the cement is a cold-curing cement such as polymethylmethacrylate (PMMA).
3. A method as claimed in claim 1 or 2 wherein the ultrasonic frequency is approximately 20KHz.
- 15 4. A method of removing a prosthesis cemented into a bone including the steps of
  - (a) applying an ultrasonic frequency to the prosthesis at such a frequency to cause fatigue fracture of bonding between the bone and cement, and between prosthesis  
20 and cement,
  - (b) applying an ultrasonic frequency to the prosthesis to cause cavitation by negative (tensile) pressure wave front advancing through water found in the interface between the prosthesis, cement, and bone,
  - 25 (c) applying an ultrasonic frequency to the prosthesis to cause thermal softening of the cement, and
  - (d) removing the prosthesis.
5. A method as claimed in claim 4 wherein the frequency used for steps (a) and (c) is approximately 500KHz and the  
30 frequency for step (b) is approximately 20KHz.
6. A method as claimed in claim 4 or 5 wherein after breaking the bond between the prosthesis and cement, the prosthesis is cooled to a temperature to shrink the prosthesis with respect to the bone without damaging living  
35 tissue to assist removal of the prosthesis.
7. An ultrasound apparatus including an ultrasonic

transducer connected to a conductive body having attachment means for attaching said body to a prosthesis, and controlling means for controlling the resonant frequency of said transducer.

- 5 8. An ultrasound apparatus as claimed in claim 7 wherein the attachment means comprise a pair of adjustable jaws for gripping the prosthesis or four equi-circumferentially spaced adjustable jaws for gripping the prosthesis.
9. An ultrasound apparatus as claimed in claim 8 wherein  
10 an adjustable clamp is provided for enabling the prosthesis to be securely gripped by the jaws.
10. An ultrasound apparatus as claimed in claim 9 wherein said clamp is a pneumatic clamp connected to a source of compressed air.
- 15 11. An ultrasound apparatus as claimed in claim 10 wherein a torque limiting device is provided to limit the grip provided by said jaws.
12. An ultrasound apparatus as claimed in any of claims 7 to 11 wherein resonance sensor means is provided for  
20 detecting the resonant frequency of the ultrasonic transducer, said resonance sensor means being connected to said controlling means, whereby in dependence upon the output of said resonance sensor means, said controlling means adjusts the resonant frequency for maximum  
25 efficiency.
13. An ultrasound apparatus as claimed in any of claims 7 to 12 wherein said conductive body is provided with cooling means whereby said prosthesis may be shrunk to assist removal in revision surgery.
- 30 14. An ultrasound apparatus as claimed in claim 13 wherein said cooling means is integrally formed with said body and conveniently is supplied from a source of cooled or liquid air.
15. An ultrasound apparatus as claimed in claim 12 wherein  
35 the sensor means includes a heat detector for detecting the temperature of the prosthesis, which said heat detector is

connected to apply signals indicative thereof to said control means, whereby the temperature of said prosthesis is regulated to a desired temperature.

16. A method as claimed in claim 1 and substantially as  
5 herein described with reference to and as shown in the accompanying drawings.

17. A method as claimed in claim 4 and substantially as herein described with reference to and as shown in the accompanying drawings.

10 18. An ultrasound apparatus substantially as herein described with reference to and as shown in Figure 2 of the accompanying drawings.



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(12) **United States Patent**  
**Spiegelberg et al.**

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(54) **SYSTEM AND METHODS FOR REDUCING INTERFACIAL POROSITY IN CEMENTS**

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(\*) **Notice:** Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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(51) **Int. Cl.<sup>7</sup>** ..... **A61F 2/32**

(52) **U.S. Cl.** ..... **623/22.12; 606/92; 606/99**

(58) **Field of Search** ..... **623/22.12; 606/92, 606/99**

(56) **References Cited**

**U.S. PATENT DOCUMENTS**

4,837,279 A	6/1989	Arroyo	525/193
4,977,115 A	12/1990	Klein et al.	501/107
5,037,442 A *	8/1991	Wintermantel et al.	623/23.16
5,045,054 A	9/1991	Hood et al.	604/22
5,284,484 A *	2/1994	Hood et al.	606/99
5,382,251 A *	1/1995	Hood et al.	606/99
5,456,686 A *	10/1995	Klapper et al.	606/99
5,480,450 A	1/1996	James et al.	623/23
5,536,266 A *	7/1996	Young et al.	606/27
5,681,872 A *	10/1997	Erbe	523/114

5,885,495 A	3/1999	Ibar	264/69
5,913,899 A	6/1999	Barrett et al.	623/18
6,005,163 A	12/1999	Tepic	623/16
6,136,035 A	10/2000	Lob et al.	623/23
6,139,584 A	10/2000	Ochoa et al.	623/23.46
6,165,177 A *	12/2000	Wilson et al.	606/100
6,203,747 B1	3/2001	Grunitz	264/443
6,210,030 B1	4/2001	Ibar	366/78

**FOREIGN PATENT DOCUMENTS**

GB	2277448 A	11/1994
WO	WO 90 04953	5/1990

**OTHER PUBLICATIONS**

Bundy, K. J., & Penn R. W., "The effect of surface preparation on metal/bone cement interfacial strength," *J. of Biomedical Research*, vol. 21, 773-805 (1987).

(Continued)

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(57)

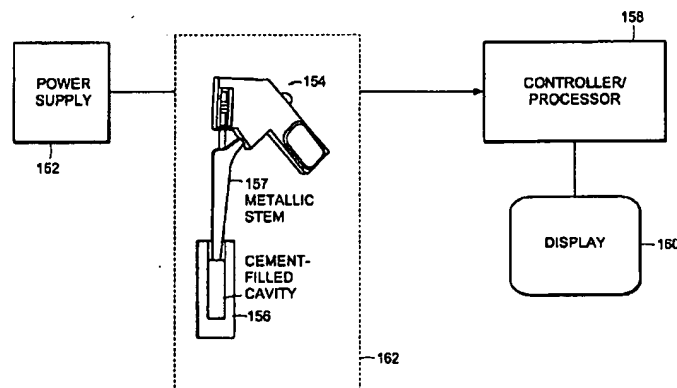
**ABSTRACT**

The present invention provides a system and a method for reducing pores, or air pockets, that form at the interface between the material used to attach or adhere the surface of a component, such as a prosthesis, to a site.

A preferred embodiment of the invention includes an actuator that controls a coupler which transmits energy to a prosthesis being inserted into a material to reduce porosity at an interface between the prosthesis and the material.

The system of the present invention can include an oscillating hand-held device that vibrates the stem component of an orthopedic prosthesis at a particular frequency and amplitude. The device is typically held by the hand of the surgeon, who guides the vibrating prosthesis into the cement-filled medullary cavity.

**82 Claims, 32 Drawing Sheets**



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pores in both FIG. 29A and 29B, and the relatively smaller size of the interfacial structures in FIG. 29B. The scale bars represent a length of 500 microns.

The claims should not be read as limited to the described order or elements unless stated to that effect. Therefore, all embodiments that come within the scope and spirit of the following claims and equivalents thereto are claimed as the invention.

What is claimed:

1. A device for implanting a prosthesis comprising:  
an actuator having a coupler that connects to a prosthesis, the prosthesis having an interface surface to be inserted into a material during implantation, the actuator comprising a housing having a transducer coupled to the prosthesis to actuate movement of the prosthesis, wherein the transducer induces vibration in the prosthesis in a range between 1 radian/second and 1000 radians/second to reduce porosity of the material at the interface surface.
2. The device of claim 1 wherein the transducer actuates vibration of the prosthesis during insertion into the material.
3. The device of claim 1 further comprising a control circuit within the housing that is electrically connected to the transducer.
4. The device of claim 1 further comprising a battery within the housing.
5. The device of claim 1 wherein the coupler comprises a thermal coupler connected to the prosthesis to control a temperature of the prosthesis.
6. The device of claim 5 further comprising a temperature sensor that measures the temperature of the prosthesis.
7. The device of claim 5 further comprising a temperature control circuit within the housing.
8. The device of claim 1 wherein the material further comprises a curable cement, the cement being inserted into a cavity in a bone of a patient.
9. The device of claim 1 further comprising a sterile sleeve extending over a housing for the actuator.
10. The device of claim 1 further comprising an actuator housing having a connector to an external power supply.
11. The device of claim 1 further comprising an actuator housing having a connector to an external control module that controls an operational parameter of the actuator.
12. The device of claim 3 wherein the control circuit comprises an oscillator, an amplifier and a processor connected to the amplifier and oscillator.
13. The device of claim 1 wherein the transducer comprises a piezoelectric driver.
14. The device of claim 1 wherein the transducer comprises a coil and a rod moving within the coil.
15. The device of claim 1 wherein the coupler comprises a pin in contact with the transducer and the prosthesis.
16. The device of claim 5 wherein the thermal coupler comprises a Peltier cell.
17. The device of claim 1 further comprising an accelerometer that measures movement of the coupler.
18. The device of claim 1 further comprising an insertion device that controls insertion of the prosthesis into the material.
19. A device for implanting a prosthesis in a patient comprising:  
a housing having an actuator, and a coupler;  
a prosthesis held by the housing such that the prosthesis contacts the coupler, the prosthesis having an interface surface;  
a transducer coupled to the prosthesis to actuate movement of the prosthesis; and

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a curable adhering material, wherein the transducer induces vibration in the prosthesis in a range between 1 radian/second and 1000 radians/second to reduce porosity of the material at the interface surface.

20. The device of claim 19 wherein the transducer actuates vibration of the prosthesis during insertion into the material.
21. The device of claim 19 further comprising a control circuit within the housing that is electrically connected to the transducer.
22. The device of claim 19 further comprising a battery within the housing and an external power supply.
23. The device of claim 19 wherein the coupler comprises a thermal coupler connected to the prosthesis to control a temperature of the prosthesis.
24. The device of claim 23 further comprising a temperature sensor that measures the temperature of the prosthesis.
25. The device of claim 23 further comprising a temperature control circuit within the housing.
26. The device of claim 19 wherein the material further comprises a curable cement, the cement being inserted into a cavity in a bone of a patient.
27. A device to reduce porosity at an interface between a bone cement and an orthopedic implant comprising:  
an oscillating device that drives movement along a selected axis of the implant, the movement having a selected frequency between 1 and 1000 radians/second and selected amplitude, the oscillating device in communication with a transducer to actuate movement of the orthopedic implant.
28. The device of claim 27 wherein the oscillating device drives a plurality of frequencies and the implant has a precoating.
29. The device of claim 27 further comprising a temperature controller having an inductive heater that controls a temperature of the implant in conjunction with vibration of the implant during insertion.
30. The device of claim 27 wherein the orthopedic implant is a femoral stem.
31. The device in claim 27 wherein the orthopedic implant is a tibia tray.
32. The device in claim 27 wherein the orthopedic implant is an acetabular shell.
33. The device of claim 27 wherein the amplitude is between 1 and 500  $\mu\text{m}$ .
34. The device of claim 27 wherein the insertion rate is between 0.1 and 5 cm/sec.
35. The device of claim 27 wherein the oscillating device comprises a servomotor driven oscillator.
36. The device of claim 27 wherein the oscillating device is an air-driven cam.
37. The device of claim 27 wherein the device comprises a hand-held housing.
38. The device of claim 27 further comprising a connection to a data processor and a display.
39. The device of claim 37 wherein the hand-held device comprises a port to receive a proximal end of the implant and a second port through which a pin extends along the selected axis to contact a surface of the implant.
40. The device of claim 27 further comprising a manually actuated switch on a housing to control the oscillating device.
41. The device of claim 27 wherein the oscillating device includes a control circuit, an accelerometer and a feedback circuit.
42. The device of claim 27 wherein the oscillating device comprises a rotating cam driven by a motor.

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43. The device of claim 27 further comprising a mounting block in which a proximal end of the implant is mounted and an actuator to impart rotational oscillation to the distal end of the implant.

44. The device of claim 27 further comprising mounting pins that attach the device at a surgical site.

45. The device of claim 27 further comprising a programmable insertion device.

46. The device of claim 27 further comprising a disposable sterile sleeve.

47. The device of claim 39 wherein the pin is spring loaded.

48. A device for implanting a prosthesis comprising:

an actuator having a coupler that connects to a prosthesis, the actuator having an oscillator to generate oscillations at a determined frequency and amplitude, the prosthesis having an interface surface to be inserted into a material during implantation, the prosthesis being actuated at the determined frequency and amplitude to reduce porosity of the material at the interface surface and wherein the coupler comprises a thermal coupler connected to the prosthesis to control a temperature of the prosthesis.

49. The device of claim 48 wherein the actuator comprises a housing having a transducer coupled to the prosthesis to actuate movement of the prosthesis.

50. The device of claim 49 wherein the transducer actuates vibration of the prosthesis during insertion into the material.

51. The device of claim 49 further comprising a control circuit within the housing that is electrically connected to the transducer.

52. The device of claim 49 further comprising a battery within the housing.

53. The device of claim 48 further comprising a temperature sensor that measures the temperature of the prosthesis.

54. The device of claim 49 further comprising a temperature control circuit within the housing.

55. The device of claim 48 wherein the material further comprises a curable cement, the cement being inserted into a cavity in a bone of a patient.

56. The device of claim 49 wherein the transducer induces vibration in the prosthesis in a range between 1 radian/second and 1000 radians/second.

57. The device of claim 48 further comprising a sterile sleeve extending over a housing for the actuator.

58. The device of claim 48 further comprising an actuator housing having a connector to an external power supply.

59. The device of claim 48 further comprising an actuator housing having a connector to an external control module that controls an operational parameter of the actuator.

60. The device of claim 51 wherein the control circuit comprises an oscillator, an amplifier and a processor connected to the amplifier and oscillator.

61. The device of claim 49 wherein the transducer comprises a piezoelectric driver.

62. The device of claim 49 wherein the transducer comprises a coil and a rod moving within the coil.

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63. The device of claim 49 wherein the coupler comprises a pin in contact with the transducer and the prosthesis.

64. The device of claim 48 wherein the thermal coupler comprises a Peltier cell.

65. The device of claim 49 further comprising an accelerometer that measures movement of the coupler.

66. The device of claim 48 further comprising an insertion device that controls insertion of the prosthesis into the material.

67. A device to reduce porosity at an interface between a bone cement and an orthopedic implant comprising:

an oscillating device that drives movement along a selected axis of the implant, the movement having a selected frequency and amplitude, the oscillating device in communication with a transducer to actuate movement of the orthopedic implant, wherein the insertion rate of the orthopedic implant is between 0.1 and 10 cm/sec.

68. The device of claim 67 wherein the oscillating device drives a plurality of frequencies and the implant has a precoating.

69. The device of claim 67 further comprising a temperature controller having an inductive heater that controls a temperature of the implant in conjunction with vibration of the implant during insertion.

70. The device of claim 67 wherein the orthopedic implant is a femoral stem.

71. The device in claim 67 wherein the orthopedic implant is a tibia tray.

72. The device in claim 67 wherein the orthopedic implant is an acetabular shell.

73. The device of claim 67 wherein the frequency is between 1 and 1000 rad/sec.

74. The device of claim 67 wherein the amplitude is between 1 and 500  $\mu\text{m}$ .

75. The device of claim 67 wherein the oscillating device comprises a servomotor driven oscillator.

76. The device of claim 67 wherein the oscillating device is an air-driven cam.

77. The device of claim 67 wherein the device comprises a hand-held housing.

78. The device of claim 67 further comprising a connection to a data processor and a display.

79. The device of claim 77 wherein the hand-held device comprises a port to receive a proximal end of the implant and a second port through which a pin extends along the selected axis to contact a surface of the implant.

80. The device of claim 67 further comprising a manually actuated switch on a housing to control the oscillating device.

81. The device of claim 67 wherein the oscillating device includes a control circuit, an accelerometer and a feedback circuit.

82. The device of claim 67 wherein the oscillating device comprises a rotating cam driven by a motor.

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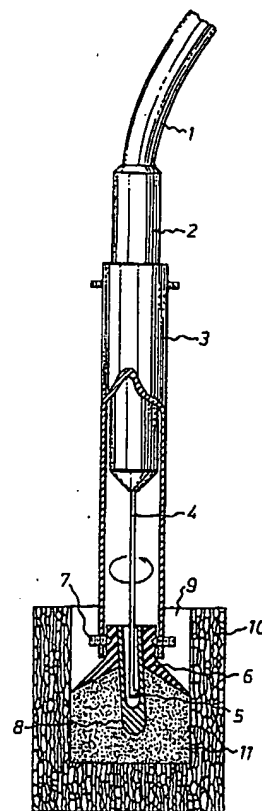
## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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A61F 2/28, A61L 25/00		(43) International Publication Date:	17 May 1990 (17.05.90)
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(22) International Filing Date: 10 November 1989 (10.11.89)			
(30) Priority data: 8804078-7 11 November 1988 (11.11.88) SE			
(71)(72) Applicant and Inventor: NILSSON, Magnus [SE/SE]; Allmogevägen 118, S-352 53 Växjö (SE).			
(74) Agent: AWAPATENT AB; Box 5117, S-200 71 Malmö (SE).			
(81) Designated States: AT, AT (European patent), AU, BB, BE (European patent), BF (OAPI patent), BG, BJ (OAPI patent), BR, CF (OAPI patent), CG (OAPI patent), CH, CH (European patent), CM (OAPI patent), DE, DE (European patent), DK, FI, FR (European patent), GA (OAPI patent), GB, GB (European patent), HU, IT (European patent), JP, KP, KR, LK, LU, LU (European patent), MC, MG, ML (OAPI patent), MR (OAPI patent), MW, NL, NL (European patent),			

**(54) Title: METHOD AND APPARATUS FOR WORKING BONE CEMENT FOR FIXING A PROSTHESIS IN A BONE**

**(57) Abstract**

In a method for working bone cement (11) placed in a cavity (9) of a bone (10), for instance in the medullary canal of the femur, for fixing a prosthesis in the cavity, the bone cement (11) placed in the cavity (9) is vibrated mechanically. A device for carrying out this method has a vibrating means (8) which is adapted to vibrate the bone cement (11) placed in the cavity (9).





## CLAIMS

1. A method for working bone cement (11) placed in a  
5 cavity (9) of a bone (10), for instance in the medullary  
canal of the femur, for fixing a prosthesis in said cavity,  
c h a r a c t e r i s e d in that the bone cement  
(11) placed in said cavity (9) is vibrated mechanically.
2. Method as claimed in claim 1, c h a r a c t e r -  
10 i s e d in that the bone cement (11) placed in said cavity  
(9) is subjected to a slight pressure while being vibrated.
3. A device for working bone cement (11) placed in a  
cavity (9) of a bone (11), for instance in the medullary  
15 canal of the femur, for fixing a prosthesis in said cavity,  
c h a r a c t e r i s e d by vibrating means (8)  
adapted to vibrate the bone cement (11) placed in said cavity  
(9).
4. Device as claimed in claim 3, c h a r a c t e r -  
20 i s e d in that the vibrating means (8) is adapted to execute  
a rotary movement.
5. Device as claimed in claim 3 or 4, c h a r a c -  
t e r i s e d by pressure loading means (6) having a  
cross-sectional shape corresponding to that of the cavity  
25 ty (9), and adapted to be introduced in the cavity to be  
pressed against the bone cement (11) placed therein.

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# INTERNATIONAL SEARCH REPORT

International Application No PCT/SE 89/00648

<b>I. CLASSIFICATION OF SUBJECT MATTER</b> (if several classification symbols apply, indicate all) *		
According to International Patent Classification (IPC) or to both National Classification and IPC IPC5: A 61 F 2/28, A 61 L 25/00		
<b>II. FIELDS SEARCHED</b>		
Minimum Documentation Searched <sup>7</sup>		
Classification System <sup>1</sup>	Classification Symbols	
IPC5	A 61 F; A 61 L	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched <sup>8</sup>		
SE,DK,FI,NO classes as above		
<b>III. DOCUMENTS CONSIDERED TO BE RELEVANT <sup>9</sup></b>		
Category <sup>9</sup>	Citation of Document, <sup>11</sup> with indication, where appropriate, of the relevant passages <sup>12</sup>	Relevant to Claim No. <sup>13</sup>
A	SE, A, 8701313-2 (AB IDEA) 1 October 1988, see the whole document --	1-3
A	EP, A2, 0093560 (HOWMEDICA INC.) 9 November 1983, see the whole document --	1,3,5
A	GB, A, 2104390 (UNIVERSITY OF EXETER) 9 March 1983, see the whole document --	1-3,5
A	US, A, 4787751 (BAKELS) 29 November 1988, see the whole document -- -----	1
<p>* Special categories of cited documents: <sup>10</sup></p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&amp;" document member of the same patent family</p>		
<b>IV. CERTIFICATION</b>		
Date of the Actual Completion of the International Search 23rd January 1990	Date of Mailing of this International Search Report 1990 -01- 2 6	
International Searching Authority SWEDISH PATENT OFFICE	Signature of Authorized Officer Leif Karnsäter <i>Leif Karnsäter</i>	

Form PCT/ISA/210 (second sheet) (January 1985)

**Relevant Technical Fields**

- (i) UK Cl (Ed.M) A5R (RAP, RAT)  
(ii) Int Cl (Ed.5) A61B 19/00, A61F 2/46

Search Examiner  
L V THOMAS

Date of completion of Search  
21 JULY 1994

**Databases (see below)**

(i) UK Patent Office collections of GB, EP, WO and US patent specifications.

Documents considered relevant following a search in respect of Claims :-  
1-6, 16, 17

(ii) ONLINE DATABASES: WPI, MEDLINE

**Categories of documents**

- X:** Document indicating lack of novelty or of inventive step. **P:** Document published on or after the declared priority date but before the filing date of the present application.  
**Y:** Document indicating lack of inventive step if combined with one or more other documents of the same category. **E:** Patent document published on or after, but with priority date earlier than, the filing date of the present application.  
**A:** Document indicating technological background and/or state of the art. **&:** Member of the same patent family; corresponding document.

Category	Identity of document and relevant passages	Relevant to claim(s)
X	WO 92/22259 A1 (ADVANCED OSSEOUX TECH) see line 16 page 14-line 13, page 15 and lines 7-21 page 32	4
X	WO 91/11965 A1 (ADVANCED OSSEOUX TECH) see line 35 page 4-line 12 page 5 and lines 4-21 page 8	4
X	WO 90/04953 A1 (NILSSON) see lines 10-35 page 3	1,2
X	US 5019083 (KLAPPER ET AL) see lines 10-63 column 4 and line 54 column 5 line 3 column 6	4
X	US 4248232 (ENGDBRECHT ET AL) see lines 10-45 column 4	4

**Databases:** The UK Patent Office database comprises classified collections of GB, EP, WO and US patent specifications as outlined periodically in the Official Journal (Patents). The on-line databases considered for search are also listed periodically in the Official Journal (Patents).

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(71) Applicant and

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(74) Agent: DARE, Heldl, A.; Brinks Hofer Gilson & Lione, P.O.Box 10087, Chicago, IL 60610 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN,

CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

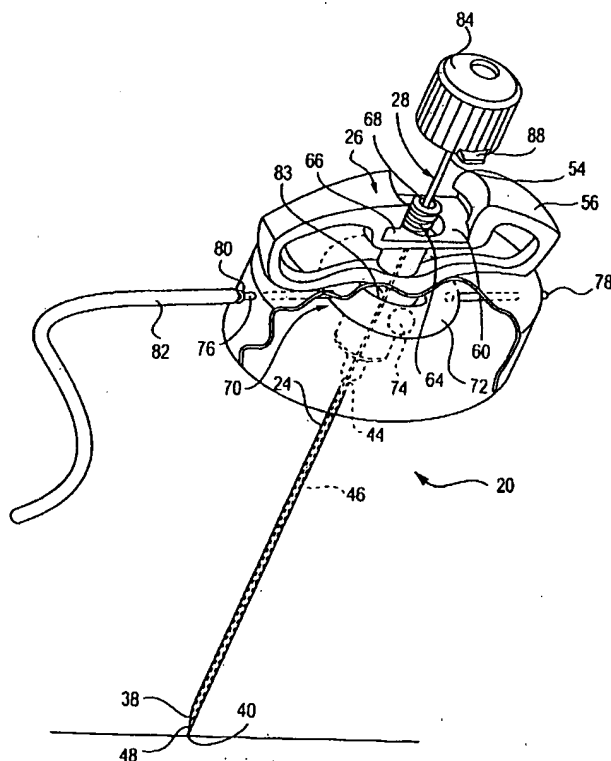
(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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[Continued on next page]

(54) Title: CEMENT DELIVERY NEEDLE



(57) Abstract: A cement delivery needle apparatus (20) and a method of flowing a bone cement through a vertebroplasty needle apparatus are provided. The cement delivery needle apparatus (20) includes a sheath (24) and a handle (26). The sheath (24) has an inlet (44) to receive a bone cement and an outlet (40) for expressing the cement into a vertebral body. The handle (26) extends from the sheath (24) and includes a vibration assembly (70) for agitating the cement. The method includes providing a bone cement source to the needle. The method further includes providing a vibration assembly associated with a handle of the needle, agitating the cement with the vibration assembly and injecting the cement through the sheath.

WO 2006/031490 A1

## INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US2005/031605

## A. CLASSIFICATION OF SUBJECT MATTER

A61B17/88 A61F2/46

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/018292 A1 (KUSLICH STEPHEN D ET AL) 23 January 2003 (2003-01-23) page 1, paragraph 3-12 page 2, paragraphs 19,34 page 3, paragraph 43-45 figures 2,7,8	1,3,7-9
Y		12-14
X	US 6 149 655 A (CONSTANTZ ET AL) 21 November 2000 (2000-11-21) column 1, line 60 - column 2, line 22 column 9, line 46 - column 10, line 19 column 22, line 43 - column 27, line 64 figures 5,29-34	1,3,9,14
A		11
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☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

## \* Special categories of cited documents:

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
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- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*G\* document member of the same patent family

Date of the actual completion of the international search

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Name and mailing address of the ISA

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## INTERNATIONAL SEARCH REPORT

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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 03/094805 A (SCIMED LIFE SYSTEMS, INC) 20 November 2003 (2003-11-20) page 1, line 5 - page 2, line 19 page 3, line 14 - page 4, line 29 page 12, lines 12-23 page 13, line 6 - page 14, line 28 figure 4A	12, 14
A	-----	1, 3
Y	EP 1 212 993 A (STRYKER TRAUMA GMBH) 12 June 2002 (2002-06-12) column 1, paragraphs 7, 8 figure 2	13
A	-----	1
P, X	WO 2005/025450 A (SKELETAL KINETICS, LLC; CONSTANTZ, BRENT R; DELANEY, DAVID; YETKINLER,) 24 March 2005 (2005-03-24) page 1, line 10 - page 3, line 8 page 5, line 21 - page 6, line 30 page 8, line 28 - page 9, line 11 page 22, line 24 - page 23, line 12 page 24, line 3 - page 28, line 30 figures 1-3, 5A	1, 3-9, 12, 14

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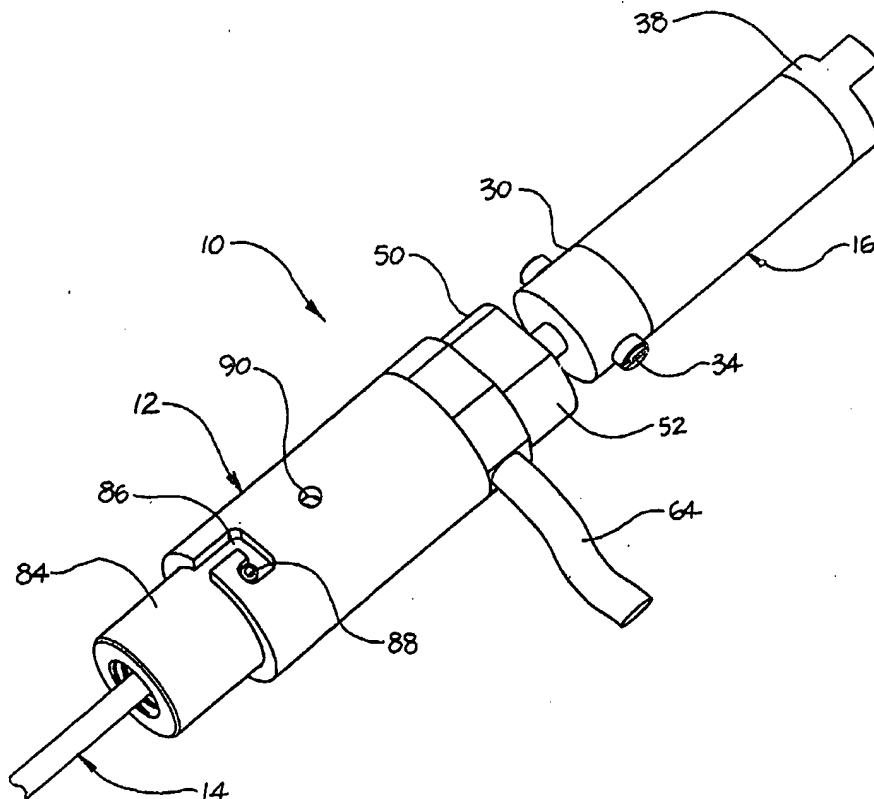
US 20030018292A1

(19) **United States**(12) **Patent Application Publication** (10) **Pub. No.: US 2003/0018292 A1**  
Kuslich et al. (43) **Pub. Date: Jan. 23, 2003**(54) **DEVICE FOR INSERTING FILL MATERIAL PARTICLES INTO BODY CAVITIES**(22) Filed: **Jul. 20, 2001****Publication Classification**(76) Inventors: **Stephen D. Kuslich**, Stillwater, MN  
(US); **Francis Peterson**, Prescott, WI  
(US); **Joseph E. Gleason**, Eagan, MN  
(US)(51) **Int. Cl.<sup>7</sup>** ..... **A61F 5/04**(52) **U.S. Cl.** ..... **604/11**

Correspondence Address:

**VIDAS, ARRETT & STEINKRAUS, P.A.**  
**6109 BLUE CIRCLE DRIVE**  
**SUITE 2000**  
**MINNETONKA, MN 55343-9185 (US)**(57) **ABSTRACT**

An instrument for filling cavities in a body, such as a cavity within a reamed out spinal disc, with beads includes a cyclical agitator that functions to prompt the introduction of one bead at a time through the fill tube to prevent clogging and to promote compaction within the cavity.

(21) Appl. No.: **09/909,668**

controlled. Such control will allow an operator to control or avoid inadvertent fracture or other potential damage to the particles of fill material 40. In addition, inadvertent contact with the tissue of the operating site 96 may also be reduced.

[0060] In addition to being directed to the specific combinations of features claimed below, the invention is also directed to embodiments having other combinations of the dependent features claimed below and other combinations of the features described above. The above disclosure is intended to be illustrative and not exhaustive. This description will suggest many variations and alternatives to one of ordinary skill in this art. All these alternatives and variations are intended to be included within the scope of the claims where the term "comprising" means "including, but not limited to". Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the claims.

[0061] Further, the particular features presented in the dependent claims can be combined with each other in other manners within the scope of the invention such that the invention should be recognized as also specifically directed to other embodiments having any other possible combination of the features of the dependent claims. For instance, for purposes of claim publication, any dependent claim which follows should be taken as alternatively written in a multiple dependent form from all prior claims which possess all antecedents referenced in such dependent claim if such multiple dependent format is an accepted format within the jurisdiction (e.g. each claim depending directly from claim 1 should be alternatively taken as depending from all previous claims). In jurisdictions where multiple dependent claim formats are restricted, the following dependent claims should each be also taken as alternatively written in each singly dependent claim format which creates a dependency from a prior antecedent-possessing claim other than the specific claim listed in such dependent claim below (e.g. claim 3 may be taken as alternatively dependent from claim 2; claim 5 may be taken as alternatively dependent on claim 3; etc.).

1. A device for inserting particles of fill material into a body cavity comprising:

a reservoir, the reservoir defining a chamber, the chamber constructed and arranged to contain a predetermined volume of the particles of fill material, the reservoir having an opening at one end through which the particles may exit the chamber, the opening slot constructed and arranged to allow only one particle at a time to exit the chamber;

an injection cylinder, the injection cylinder having a proximal end and a distal end, the proximal end being engaged to the reservoir, the injection cylinder defining a hollow chamber being open at both ends, the proximal end of the injection cylinder being coupled to the reservoir thereby defining a coupled assembly, the hollow chamber being in fluid communication with the opening, the hollow chamber sized to receive the particles from the opening and pass the particles therethrough; and

a reciprocator device; the reciprocator device operatively engaged to at least a portion of the injection cylinder,

the reciprocator device constructed and arranged to reciprocatingly move the coupled assembly thereby causing the particles of fill material to exit the chamber through the opening one particle at a time and pass the particles through the hollow chamber.

2. The device of claim 1 wherein the hollow chamber is sized to pass the particles one at a time therethrough.

3. The device of claim 1 wherein the hollow chamber is sized to pass the particles in a single file manner therethrough.

4. The device of claim 1 wherein the hollow chamber is sized to pass a plurality of the particles in a single file manner therethrough.

5. The device of claim 1 wherein the reciprocator device defines a longitudinally oriented hollow passage which extends therethrough, the injector cylinder having a piston member fixedly engaged thereto, the reciprocator device being constructed and arranged to reciprocatingly move the piston member between a first position and a second position within a first portion of the longitudinally oriented hollow passage.

6. The device of claim 5 wherein the piston member further comprises a slidable piston seal, the slidable piston seal slidably sealing the piston member to the first portion of the longitudinally oriented hollow passage.

7. The device of claim 6 wherein the longitudinally oriented hollow passage further comprises a proximal sliding seal assembly, the proximal sliding seal assembly slidably sealing the injection cylinder proximal to the piston member to a proximal opening of the first portion of the longitudinally oriented hollow passage.

8. The device of claim 7 wherein reciprocator device further comprises a fluid injection port, the fluid injection port being positioned proximal of the piston member and providing fluid communication between the first portion of the longitudinally oriented hollow passage and a fluid source.

9. The device of claim 8 wherein the fluid source is constructed and arranged to selectively inject a fluid into the first portion of the longitudinally oriented hollow passage through the fluid injection port, the fluid providing a sufficient pressure to move the piston member from the first position to the second position.

10. The device of claim 9 further comprising a biasing member, the biasing member being positioned in a second portion of the longitudinally oriented hollow passage distally positioned relative to the first portion of the longitudinally oriented hollow passage, the biasing member being biasedly engaged between the piston member and a distal stop member, the biasing member exerting a sufficient biasing force to move the piston member from the second position to the first position.

11. The device of claim 10 wherein the distal stop member is engaged to a distal end of the reciprocator device, the distal stop member defining an opening, the opening having a diameter sized to slidably pass the cylindrical injector therethrough, the opening having a diameter smaller than the piston member.

12. The device of claim 11 wherein the distal stop member is removably engaged to the distal end of the reciprocator device.

13. The device of claim 12 wherein the distal stop member further comprises at least one engagement member, the at



least one engagement member constructed and arranged to be removably engaged to a distal end of the reciprocator device.

14. The device of claim 13 wherein the distal end of the reciprocator device comprises at least one engagement channel, the at least one engagement channel constructed and arranged to removably receive the at least one engagement member.

15. The device of claim 9 wherein the fluid source is a fluid pump selected from the group consisting of a pneumatic pump, a hydraulic pump, and any combination thereof.

16. The device of claim 7 wherein the proximal sliding seal assembly is constructed and arranged to release fluid pressure from the first portion of the longitudinally oriented hollow passage after the piston member is moved from the first position to the second position therein.

17. The device of claim 1 wherein the reservoir is transparent.

18. The device of claim 1 wherein the reservoir further comprises a retaining collar, the opening being integral with the retaining collar.

19. The device of claim 18 wherein the retaining collar is removably engaged to the reservoir chamber.

20. The device of claim 19 wherein the proximal end of the injection cylinder is engaged to the retaining collar.

21. The device of claim 20 wherein the proximal end of the injection cylinder is removably engaged to the retaining collar.

22. The device of claim 21 wherein the retaining collar further comprises at least one fastening member, the at least one fastening member removably retaining the proximal end of the injection cylinder to the retaining collar.

23. The device of claim 1 wherein the reservoir defines a reservoir opening for inserting the fill material into the reservoir chamber.

24. The device of claim 23 further comprising a removable reservoir plug, the removable plug constructed and arranged to be removably engaged to the reservoir opening.

25. The device of claim 1 wherein the hollow chamber has a diameter of about 0.5 to about 5 mm.

26. The device of claim 1 wherein the particles of fill material are selected from at least one member of the group consisting of bioceramic beads, bone graft material and any combination thereof.

27. The device of claim 9 further comprising a controller device, the controller device constructed and arranged to selectively control the flow of fluid from the fluid source into the first portion of the longitudinally oriented hollow passage.

28. The device of claim 1 further comprising a depth guide, the depth guide defining a sheath, the sheath being disposed about at least a portion of the injection cylinder, a proximal end of the depth guide being engaged to at least a portion of the reciprocator device, whereby when the reciprocator device reciprocatingly moves the coupled assembly the depth guide remains substantially immobile relative to the injection cylinder.

29. The device of claim 28 wherein the depth guide is adjustably engaged to the at least a portion of the reciprocator device.

30. The device of claim 29 wherein the depth guide is threadingly engaged to the at least a portion of the reciprocator device.

31. The device of claim 28 wherein the depth guide further comprises a distal end, the distal end having a contact member engaged thereto, the contact member constructed and arranged to be disposed about at least a portion of an opening of an operating site.

32. The device of claim 32 wherein the contact member is removably engaged to the distal end of the depth guide.

33. The device of claim 32 wherein the contact member is constructed at least partially from a vibration absorbing material.

34. The device of claim 28 wherein the depth guide and the injection cylinder have a lubricant therebetween.

35. The device of claim 34 wherein the lubricant is biocompatible.

36. A device for inserting fill material into a body cavity comprising:

a hollow injection cylinder, a reservoir for containing the fill material, and a central housing,

the hollow injection cylinder being in fluid communication with the reservoir, the central housing defining a passage which extends therethrough, the passage being disposed about the hollow injection cylinder, the hollow injection cylinder being longitudinally moveable within the passage, the hollow injection cylinder and the central housing having at least one sliding valve seal therebetween;

at least a portion of the hollow injection cylinder having a piston member fixedly engaged thereto, the piston member having a first position and being moveable to a second position, a first portion of the passage defining a piston chamber, the piston chamber constructed and arranged to receive a predetermined quantity of fluid therein, the predetermined quantity of fluid exerting a distally acting force on the piston member;

a second portion of the passage defining a biasing chamber, the biasing chamber having a biasing member disposed between the piston member and a distal surface, the biasing member exerting a proximally acting biasing force on the piston member;

whereby, when the predetermined quantity of fluid is received into the chamber, the first distally acting force is sufficient to move the piston member in the distal direction from the first position to the second position, after the piston member is moved to the second position at least a portion of the predetermined quantity of fluid is released, thereafter the proximally acting force is sufficient to return the piston member from the second position to the first position.

\* \* \* \* \*



US006626912B2

**(12) United States Patent**  
**Speitling****(10) Patent No.: US 6,626,912 B2**  
**(45) Date of Patent: Sep. 30, 2003****(54) PROCESS FOR MIXING AND DISPENSING A FLOWABLE SUBSTANCE****(75) Inventor: Andreas Werner Speitling, Kiel (DE)****(73) Assignee: Stryker Trauma GmbH (DE)****(\*) Notice:** Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

3,739,947 A	6/1973	Baumann et al.
3,749,371 A	7/1973	Folkenroth et al.
3,756,571 A	9/1973	Winberg
3,828,434 A	8/1974	Mosch
3,831,742 A	8/1974	Gardella et al.
3,917,062 A	11/1975	Winters
4,084,320 A	4/1978	Skeirik

(List continued on next page.)

**FOREIGN PATENT DOCUMENTS**

EP	0 976 443	2/2000
FR	2 572 677	5/1986

\* cited by examiner

*Primary Examiner*—Pedro Philogene*Assistant Examiner*—D A Bonderer**(74) Attorney, Agent, or Firm**—Lerner, David, Littenberg, Krumholz & Mentlik, LLP**(21) Appl. No.: 09/988,517****(22) Filed: Nov. 20, 2001****(65) Prior Publication Data**

US 2002/0087164 A1 Jul. 4, 2002

**(30) Foreign Application Priority Data**

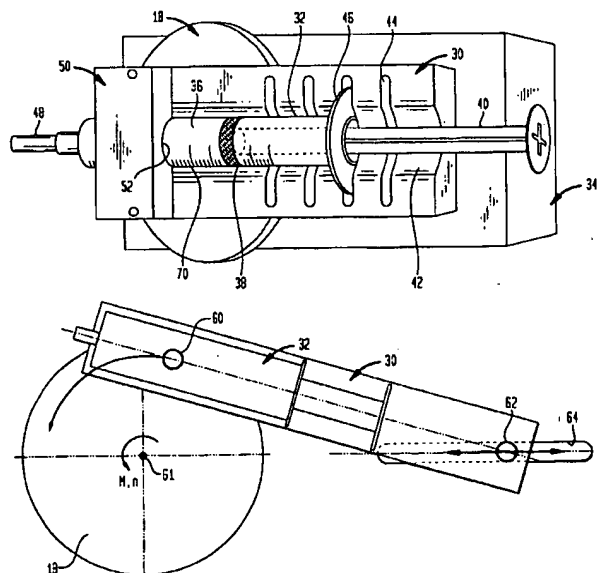
Nov. 21, 2000 (DE) ..... 100 57 616

**(51) Int. Cl.<sup>7</sup> ..... A61F 17/58; B01F 11/00****(52) U.S. Cl. .... 606/92; 366/209; 366/216; 366/218****(58) Field of Search .... 606/92, 93; 366/209, 366/216, 218, 116, 110, 210, 211, 212, 219, 237, 239, 240****(56) References Cited****U.S. PATENT DOCUMENTS**

140,280 A	*	6/1873	Keeler	366/216
1,421,016 A		6/1922	Leipold	
1,489,024 A	*	4/1924	Burnett	366/209
1,490,214 A		4/1924	Johnson	
1,686,135 A		10/1928	Hurdle	
2,151,123 A		3/1939	Lavine	
3,275,302 A		9/1966	Horton	
3,684,136 A		8/1972	Baumann	

**(57) ABSTRACT**

A process and apparatus for use in mixing and applying a flowable substance that consists of a powdered first component and a liquid second component. The mixing of the two components form a flowable substance, especially a bone cement. The apparatus uses an injection syringe. The first component is placed into the injection syringe after removing the syringe plunger and placing a closing device or cap onto the dispensing end of the syringe. The liquid component is added to the syringe, preferably from a second syringe filled with the liquid component via a hollow needle of the second syringe. The first syringe is closed at the filling with the syringe plunger under the load of sufficient air in the syringe cylinder. The components are mixed by shaking the first syringe. The lid of the first syringe is removed and a hollow needle is placed onto the first syringe and the flowable substance is delivered at a desired site.

**19 Claims, 3 Drawing Sheets**

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FIG. 2B shows a top view of the mixing device with the mounted injection syringe; and

FIG. 3 schematically shows the structure for driving a holder of the mixing device according to FIGS. 1 and 2.

#### DETAILED DESCRIPTION

FIG. 1 schematically shows a mixing device 10, as well as a rotating drive motor 12 shown with a drive spindle 14.

The mixing device 10 has a generally L-shaped base part 16, on one leg of which, on the inside, is rotatably mounted a disk 18. On the opposite side of the leg 20 is located a reducing gear 22, which is in contact with the bearing shaft (not shown) of the disk 18 via its output shaft (not shown). An input shaft 24 of the input transmission 22 has a mount 26 for mounting the drive spindle 14 of the rotating drive motor 12 in a manner adapted to rotate in unison. For coupling purposes, the mount spindle 26 is plugged on drive 14.

An oblong holder 30 for an injection syringe 32 is mounted in a linearly movable manner on the other leg 34 of base part 16 in its longitudinal direction according to the double arrow 33. A pin 60 (shown in FIG. 3) of disk 18 is in rotational connection with the lower side of holder 30. The pin 60 is attached eccentrically to the disk 18. Therefore, a rotation of the disk 18 leads to a superimposed movement from the rotation of the disk 18 and from the forced translatory movement of the holder 30.

FIG. 2 shows holder 30 more clearly. The component 34a, on which the holder 30 is mounted in a linearly movable manner, is shown somewhat differently from the one according to FIG. 1. However, this is of no importance for the mode of operation.

Moreover, disk 18, which is eccentrically linked to the lower side of the holder 30, is seen. The syringe 32 is a conventional injection syringe with a syringe cylindrical barrel 36, a plunger 38 and a plunger rod 40. On the upper side, holder 30 has a channel 42, which is almost semicircular in its cross section, into which the syringe cylinder 36 is inserted. Transverse to channel 42 are grooves 44 which are formed at intervals and which accommodate a flange 46 at the end of cylinder 36. The dispensing end of syringe 32 is closed by means of a cap 48. A chuck or web-like component 50 has a channel-like recess 52, which accommodates a part of syringe cylinder 36, if it, as is shown in FIG. 2, is placed above syringe 32 in order to clamp same. The fastening of web 50 to holder 30 is carried out by means of screws or similar detachable fastening means.

A syringe like the syringe 32 is first filled outside of holder 30 and with plunger 38 removed with the two components that shall be mixed, e.g., a powdered bone cement component and a liquid component, one after the other. Subsequently, the plunger is pushed in under the load of sufficient clearance. Syringe 32, which has been closed by means of the cap 48, is then inserted into the holder 30 and fastened. The mixing movement can then be set in operation by applying a torque via the input transmission 22. A second container such as syringe 100 shown in FIG. 2A contains the liquid component which container may be supplied as part of a kit.

A structure, as is schematically shown in FIG. 3, is used for the mixing movement. Disk 18 is coupled via pin 60 to holder 30, which holder has a pin 62, which is guided linearly in an oblong slot 64 of the component 34a. With the rotation of disk 18 the syringe 32 with holder 30 performs a pivoting or eccentric movement around pin 62 with an amplitude, which is determined by the radius of the position

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of pin 60 from center of rotation 61. The amplitude also depends on the location of the syringe in the holder or the location of the holder on pin 60. At the same time, with a rotation of disk 18, pin 60 is moved back and forth in the longitudinal slot 64, whereby the stroke likewise depends on the radius of the position of pin 60.

After the mixing process which lasts, e.g., 30 seconds, the syringe 32 is removed from the holder 30 and fed into a dispensing device, which is able to accommodate the syringe with plunger. Thus, the front end of syringe 32 is manually accessible, so that the cap 48 can be removed and a hollow needle of a predetermined size can be placed thereon. The dispensing device which may be in the form of a typical caulking gun (not shown) has a feed bar, which cooperates with the plunger or the plunger rod 40 of the syringe 32. The feed bar, for its part, is actuated by a hand lever via a suitable transmission. The transmission may be selected so that the entire contents of the syringe 32 can be pressed out with a single stroke of the hand lever. However, it may also be designed so that several strokes of the hand lever are necessary. Since the syringe 32 has markings 70, it can be observed how much of the contents is dispensed with a stroke of the hand lever in each case.

The bringing together of the components and the holder of the syringe in the mixing device shall last less than one minute, if possible. With corresponding rotational speed of the disk 18, a mixing can be carried out within 30 seconds. The removal of the syringe, the insertion into a dispensing device and the processing shall not last longer than 5 minutes, if possible.

For the purpose of better handling, the device shown in FIGS. 1 and 2 can be detachably fastened to a background, e.g., a table top or a special stand.

Although the invention herein has been described with reference to particular embodiments, it is to be understood that these embodiments are merely illustrative of the principles and applications of the present invention. It is therefore to be understood that numerous modifications may be made to the illustrative embodiments and that other arrangements may be devised without departing from the spirit and scope of the present invention as defined by the appended claims.

What is claimed is:

1. A process for mixing and applying a flowable substance, which consists of a powdered first component and a liquid second component comprising:

placing the first component into a generally cylindrical barrel an injection syringe having a dispensing port and placing a closing means onto the dispensing port of the syringe;

placing the liquid second component in the injection syringe with the first component;

clamping the syringe barrel to a mixer using a moveable clamp having a part-cylindrical channel therein;

mixing the components by shaking the injection syringe; and removing the closing means of the injection syringe and placing a hollow needle onto the port of the injection syringe and delivering the flowable substance at a desired site.

2. The process for mixing as set forth in claim 1, wherein the liquid component is placed into the injection syringe through the dispensing port.

3. The process for mixing as set forth in claim 1, wherein the shaking is performed in an eccentric movement.

4. The process for mixing as set forth in claim 1, wherein the closing means is a cap.

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5. A mixing device for a flowable substance consisting of a powdered first component and a liquid second component comprising:

an injection syringe having a cylindrical barrel with a plunger and a removable closing means at a dispensing end as a mixing vessel for the first and second components;

a holder for the detachable holding of said injection syringe, the holder including a moveable clamp having a cylindrical recess formed therein for engaging the syringe; and a mixing device which imparts on said holder a movement that arises from the superposition of a rotary and a translatory movement.

6. The device in accordance with claim 5, wherein an input transmission is arranged between said mixing device and an input shaft provided for inputting rotary motion to the input transmission, the input shaft mounted to a drive motor.

7. The device in accordance with claim 5 wherein said holder acts as a connecting rod of a connecting-rod device.

8. The device in accordance with claim 7, wherein an end area of said holder is eccentrically linked to a rotor, which is coupled with the output shaft of the input transmission, while the other end is mounted in a linearly movable manner.

9. The device in accordance with claim 5 wherein said closing means of said syringe is a cap.

10. The device in accordance with claim 5 wherein said holder has a mounting channel, which has, at intervals, transverse grooves for receiving a flange of said syringe cylinder.

11. A kit for mixing a bone cement made from powdered and liquid components comprising:

at least one injection syringe having a powdered component stored therein and a dispensing port;

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at least one container having a liquid component stored therein; and

a mixer having an eccentrically driven holder for receiving said injection syringe and imparting motion thereto having rotary and linear components, the holder including a moveable clamp having a cylindrical recess formed therein for engaging the syringe.

12. The kit as set forth in claim 11 further comprising at least one hollow needle for coupling to the dispensing port.

13. The kit as set forth in claim 11, wherein the powdered component is tetra-calcium phosphate and dicalcium phosphate.

14. The kit as set forth in claim 11, wherein the at least one container is a syringe.

15. The kit as set forth in claim 11 further including a rotary driver having an input shaft for driving said mixer.

16. The kit in accordance with claim 15, wherein an input transmission is arranged between said mixer and said input shaft provided for inputting rotary motion to the input transmission, the input shaft mounted to said driver, said transmission driving said mixer via an output shaft.

17. The kit in accordance with claim 16, wherein an end area of said holder is eccentrically linked to a rotor, which is coupled with the output shaft of the input transmission, while the other end is mounted in a linearly movable manner.

18. The kit in accordance with claim 11, wherein said dispensing part has a closing means in the form of a cap.

19. The kit in accordance with claim 11, wherein said holder has a mounting channel, which has, at intervals, transverse grooves for receiving a flange on a barrel of said injection syringe.

\* \* \* \* \*

45/7/64 (Item 64 from file: 350)

Derwent WPIX

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0006941790 *Drawing available*

WPI Acc no: 1994-340849/199442

Related WPI Acc No: 1993-213291

XRPX Acc No: N1994-267435

**Tip for ultrasonic surgical aspirator - with central bore which expands in dia. from surgical tip in direction of aspiration flow for length of at least quarter wavelength of device resonant frequency**

Patent Assignee: SONOKINETICS INC (SONO-N)

Inventor: WUCHINICH D G

Patent Family ( 1 patents, 1 countries )

Patent Number	Kind	Date	Application Number	Kind	Date	Update	Type
US 5358505	A	19941025	US 1991706669	A	19910529	199442	B
			US 1992964570	A	19921021		
			US 199381580	A	19930622		

Priority Applications (no., kind, date): US 1992964570 A 19921021; US 1991706669 A 19910529; US 199381580 A 19930622

Patent Details

Patent Number	Kind	Lan	Pgs	Draw	Filing Notes	
US 5358505	A	EN	13	10	C-I-P of application	US 1991706669
					Division of application	US 1992964570
					Division of patent	US 5221282

#### Alerting Abstract US A

Thermoplastics prosthetic **cement** adherent to a **bone** surface is contacted with an aspirating ultrasonically **vibrating** surgical **device**, having a centrally located bore which extends throughout the length of the **device**. The **device** is **vibrated** to provide ultrasonic **vibration** of a sufficient amplitude and frequency to melt the **cement** while simultaneously irrigating the **bone** surface. The melted **cement** and irrigant are aspirated through the bores of the **device**. The distal end of the bore expands in diameter in the direction of aspirant flow to facilitate removal of the melted **cement**. Removal of the irrigant cools heat generated by the **device**. The **device** is provided with a surgical tip and an ultrasonic transducer and the surgical trip **vibrated** from 50 to 500 microns at a frequency of from 10 to 50 kHz. The bore is selected to expand in diameter in the direction of aspirant flow from about 1 to 1000 percent. USE - Tip for ultrasonic aspirator for removing thermoplastic prosthetic **cement** from **bone**.

**Title Terms /Index Terms/Additional Words:** TIP; ULTRASONIC; SURGICAL; ASPIRATE; CENTRAL; BORE; EXPAND; DIAMETER; DIRECTION; FLOW; LENGTH; QUARTER; WAVELENGTH; **DEVICE**; RESONANCE; FREQUENCY

**Class Codes**

## International Patent Classification

IPC	Class Level	Scope	Position	Status	Version Date
A61B-017/56			Main		"Version 7"

US Classification, Issued: 606099000

File Segment: EngPI; EPI;

DWPI Class: S05; P31

Manual Codes (EPI/S-X): S05-B02

## Original Publication Data by Authority

### United States

**Publication No.** US 5358505 A (Update 199442 B)

**Publication Date:** 19941025

**Tapered tip ultrasonic aspiration method**

**Assignee:** Sonokinetics, Inc. (SONO-N)

**Inventor:** Wuchinich, David G., NY, US

**Agent:** Pennie & Edmonds

**Language:** EN (13 pages, 10 drawings)

**Application:** US 1991706669 A 19910529 (C-I-P of application)

US 1992964570 A 19921021 (Division of application)

US 199381580 A 19930622 (Local application)

**Related Publication:** US 5221282 A (Division of patent)

**Original IPC:** A61B-17/56(A)

**Current IPC:** A61B-17/56(A)

**Original US Class (main):** 60699

**Original Abstract:** A method for the melting and removal of thermoplastic prosthetic implant cement through the use of an aspirating ultrasonic surgical device is provided. The instrument defines a centrally located bore which expands in diameter from a surgical tip in the direction of aspirant flow for a length equal to at least 1/4 the wavelength corresponding to the resonant frequency of the device so as to prevent blockage by solidified cores of cement. Alternatively, the bore expands from a first uniform diameter extending from the tip end to a second uniform diameter. A compound taper at the tip end minimizes contact between the outer surface of the tube at the tip end. A novel transducer cooling system is provided by incorporating a thermally conductive, electrically insulating material between the piezoelectric crystal (which generates heat as a byproduct) and a hollow metal bolt which defines a central bore through which cooling irrigant flows to conductively remove heat generated by the crystal.

**Claim:**

2. A method for removing thermoplastic prosthetic cement from bone comprising: contacting thermoplastic prosthetic cement adherent to a bone surface with an aspirating ultrasonically vibrating surgical device, having a centrally located bore which extends throughout the length of said device; vibrating said device to provide ultrasonic vibration of a sufficient amplitude and frequency to melt said cement while simultaneously irrigating said bone surface; and aspirating said melted cement and irrigant through said bores of said device; wherein the

distal end of the bore expands in diameter in the direction of aspirant flow to facilitate removal of said melted cement and wherein removal of said irrigant cools heat generated by said device

45/7/21 (Item 21 from file: 350)

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0014710320 *Drawing available*

WPI Acc no: 2005-057929/200506

XRAM Acc no: C2005-020067

XRPX Acc No: N2005-050160

**Vibrating probe apparatus for agitating surgical fluid for removing entrapped air to provoke interdigitation between column of surgical fluid and bone wall comprises at least one fin disposed on probe tip or elongated shaft**

Patent Assignee: MYERS T H (MYER-I)

Inventor: MYERS T H

Patent Family ( 2 patents, 106 countries )

Patent Number	Kind	Date	Application Number	Kind	Date	Update	Type
WO 2004112661	A1	20041229	WO 2004US19978	A	20040621	200506	B
US 20050010231	A1	20050113	US 2003479850	P	20030620	200506	E
			US 2004873537	A	20040621		

Priority Applications (no., kind, date): US 2004873537 A 20040621; US 2003479850 P 20030620

Patent Details

Patent Number	Kind	Lan	Pgs	Draw	Filing Notes
WO 2004112661	A1	EN	36	7	
National Designated States,Original	AE AG AL AM AT AU AZ BA BB BG BR BW BY BZ CA CH CN CO CR CU CZ DE DK DM DZ EC EE EG ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NA NI NO NZ OM PG PH PL PT RO RU SC SD SE SG SK SL SY TJ TM TN TR TT TZ UA UG US UZ VC VN YU ZA ZM ZW				
Regional Designated States,Original	AT BE BG BW CH CY CZ DE DK EA EE ES FI FR GB GH GM GR HU IE IT KE LS LU MC MW MZ NA NL OA PL PT RO SD SE SI SK SL SZ TR TZ UG ZM ZW				
US 20050010231	A1	EN			Related to Provisional US 2003479850

**Alerting Abstract WO A1**

NOVELTY - A **vibrating probe apparatus** (10) comprises an elongate shaft (20) having a proximal and an opposing distal ends, a probe tip disposed upon the shaft near the distal end; and a motor (26) for producing a **vibration** within the probe tip. The proximal end is graspable for supporting and maneuvering the **apparatus**. At least one fin (34) is disposed about the probe tip or the elongate shaft extending into said fluid.

DESCRIPTION - INDEPENDENT CLAIMS are included for the following:

2. a system for **bonding** a **column** of surgical fluid to a bone wall;



3. a system for consolidating a **prosthesis**, a column of surgical fluid, and a porous bone wall into an **integrated** structure.

USE - For agitating surgical fluid for removing entrapped air to provoke interdigitation between column of surgical fluid and bone wall (claimed).

ADVANTAGE - The fins function to disrupt, coalesce into larger voids and mobilize the entrapped air voids. Also, the fins are shaped to assist in keeping the probe tip near the center of the canal, in order to deliver an evenly distributed vibration throughout the surgical fluid. Agitating the surgical fluid in vivo provides a benefit in that any air voids introduced into the canal by other procedures such as injecting the fluid or placing a **prosthesis** may be removed before the fluid hardens or cures. Vibrations in the bone and surrounding **structures** that will **propagate** inwardly from the bone walls as well as outwardly **from** the probe tip, thus creating an improved environment for laminar fluid flow and increased interdigitation. The cumulative effect of the increased interdigitation of the fluid with multiple pores results in an improved bond along the fluid-bone interface, **resulting** in more efficient **load** transfer and torsional strength. Agitation of the surgical fluid also improves the bio-mechanical characteristics of the fluid-prosthesis interface, thereby promoting more efficient transfer of forces and stresses from the prosthesis, through the fluid, to the bone. The method eliminates the need for several **steps** currently used during fourth-generation cementing technique e.g. pressurization of the **column** of surgical fluid may be no longer required. Vibrating the column of surgical fluid in vivo may provide more extrusion of the fluid into surrounding bone pores and prosthesis ridges than **would** be provided by pressurization.

DESCRIPTION OF DRAWINGS - The drawing shows the apparatus in use within a long **bone**.

10 vibrating probe apparatus

20 elongate shaft

26 motor

34 fin

120 bone wall

**Title Terms /Index Terms/Additional Words:** **VIBRATION**; **PROBE**; **APPARATUS**; **AGITATE**; **SURGICAL**; **FLUID**; **REMOVE**; **ENTRAP**; **AIR**; **PROVOKE**; **COLUMN**; **BONE**; **WALL**; **COMPRISE**; **ONE**; **FIN**; **DISPOSABLE**; **TIP**; **ELONGATE**; **SHAFT**

#### **Class Codes**

#### **International Patent Classification**

<b>IPC</b>	<b>Class Level</b>	<b>Scope</b>	<b>Position</b>	<b>Status</b>	<b>Version Date</b>
<b>A61B-017/58</b> ; <b>A61F-002/46</b>			Main		"Version 7"
<b>A61B-017/88</b>			Secondary		"Version 7"

US Classification, Issued: 606086000

File Segment: CPI; EngPI

DWPI Class: D22; P31; P32

Manual Codes (CPI/A-N): D09-C

#### **Original Publication Data by Authority**

## United States

**Publication No.** US 20050010231 A1 (Update 200506 E)

**Publication Date:** 20050113

**Method and apparatus for strengthening the biomechanical properties of implants**

**Assignee:** Myers, Thomas H., Marietta, GA, US

**Inventor:** Myers, Thomas H., Marietta, GA, US

**Agent:** ALSTON & BIRD LLP, BANK OF AMERICA PLAZA, 101 SOUTH TRYON STREET, SUITE 4000, CHARLOTTE, NC, US

**Language:** EN

**Application:** US 2003479850 P 20030620 (Related to Provisional)

US 2004873537 A 20040621 (Local application)

**Original IPC:** A61B-17/58(A)

**Current IPC:** A61B-17/58(A)

**Original US Class (main):** 60686

**Original Abstract:** A method for agitating a surgical fluid using a vibrating probe is disclosed. The agitation method drives entrapped air voids out of the surgical fluid and forces the fluid into a plurality of pores of various sizes in the adjacent bone. The vibrating apparatus in one embodiment includes a probe tip disposed upon a graspable elongate shaft and a series of fins extending into the fluid. The apparatus in one embodiment may include a set of probe tips of different shapes and sizes. The agitation and interdigitation method may facilitate any procedure involving any type of surgical fluid, with or without a prosthetic device such as an intramedullary nail or femoral prosthesis. This Abstract is provided to quickly inform a reader about the subject matter, and not for use interpreting the scope or meaning of the claims.

**Claim:** What is claimed is:

1. 1. A method of improving the structural integrity of a column of surgical fluid adjacent a bone wall having a plurality of open pores, the method comprising:
  - inserting a probe into said column of surgical fluid; and
  - vibrating said probe within said column of surgical fluid in order to drive entrapped air toward and through a surface of said fluid and to drive said surgical fluid into one or more of said plurality of open pores.

## WIPO

**Publication No.** WO 2004112661 A1 (Update 200506 B)

**Publication Date:** 20041229

**METHOD AND APPARATUS FOR STRENGTHENING THE BIOMECHANICAL PROPERTIES OF IMPLANTS**

**PROCEDE ET APPAREIL DE RENFORCEMENT DES PROPRIETES BIOCHIMIQUES D'IMPLANTS**

**Assignee:** MYERS, Thomas, H., 3240 Waldwick Way SE, Marietta, GA 30067-9123, US Residence: US

**Nationality:** US (MYER-I)

**Inventor:** MYERS, Thomas, H., 3240 Waldwick Way SE, Marietta, GA 30067-9123, US Residence: US Nationality:

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Agent: ANDERSON, J. Scott, Alston & Bird LLP, Bank of America Plaza, 101 South Tryon Street, Suite 4000, Charlotte, NC 28280-4000, US

Language: EN (36 pages, 7 drawings)

Application: WO 2004US19978 A 20040621 (Local application)

Priority: US 2003479850 P 20030620

Designated States: (National Original) AE AG AL AM AT AU AZ BA BB BG BR BW BY BZ CA CH CN CO CR CU CZ DE DK DM DZ EC EE EG ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NA NI NO NZ OM PG PH PL PT RO RU SC SD SE SG SK SL SY TJ TM TN TR TT TZ UA UG US UZ VC VN YU ZA ZM ZW

(Regional Original) AT BE BG BW CH CY CZ DE DK EA EE ES FI FR GB GH GM GR HU IE IT KE LS LU MC MW MZ NA NL OA PL PT RO SD SE SI SK SL SZ TR TZ UG ZM ZW

Original IPC: A61F-2/46(A) A61B-17/88(B)

Current IPC: A61F-2/46(A) A61B-17/88(B)

Original Abstract: A method for agitating a surgical fluid (40) using a vibrating probe is disclosed. The agitation method drives entrapped air voids (44) out of the surgical fluid and forces the fluid into a plurality of pores (130) of various sizes in the adjacent bone (100). The vibrating apparatus (10) in one embodiment includes a probe tip (30) disposed upon a graspable elongate shaft (20) and a series of fins (34) extending into the fluid. The apparatus in one embodiment may include a set of probe tips of different shapes and sizes. The agitation and interdigitation method may facilitate any procedure involving any type of surgical fluid, with or without a prosthetic device such as an intramedullary nail (356) or femoral prosthesis (358).

45/7/26 (Item 26 from file: 350)

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0014054718 *Drawing available*

WPI Acc no: 2004-237132/200422

XRPX Acc No: N2004-187894

**Void compacting apparatus for bone structure, has elongate unit with distal end positioned within void, and vibration device creating vibration at distal end of elongate unit, so that media is mixed and/or compacted within void**

Patent Assignee: SCIMED LIFE SYSTEMS INC (SCIM-N)

Inventor: BURNS M; JANSEN L P; OLSON J S W; OLSON S W

Patent Family ( 4 patents, 102 countries )

Patent Number	Kind	Date	Application Number	Kind	Date	Update	Type
US 20040024410	A1	20040205	US 2002211492	A	20020802	200422	B
WO 2004012614	A2	20040212	WO 2003US24216	A	20030801	200422	E
AU 2003269937	A1	20040223	AU 2003269937	A	20030801	200453	E
AU 2003269937	A8	20051027	AU 2003269937	A	20030801	200624	E

Priority Applications (no., kind, date): US 2002211492 A 20020802

#### Patent Details

Patent Number	Kind	Lan	Pgs	Draw	Filing Notes	
US 20040024410	A1	EN	19	15		
WO 2004012614	A2	EN				
National Designated States,Original	AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CO CR CU CZ DE DK DM DZ EC EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NI NO NZ OM PG PH PL PT RO RU SD SE SG SK SL SY TJ TM TN TR TT TZ UA UG UZ VC VN YU ZA ZM ZW					
Regional Designated States,Original	AT BE BG CH CY CZ DE DK EA EE ES FI FR GB GH GM GR HU IE IT KE LS LU MC MW MZ NL OA PT RO SD SE SI SK SL SZ TR TZ UG ZM ZW					
AU 2003269937	A1	EN			Based on OPI patent	WO 2004012614
AU 2003269937	A8	EN			Based on OPI patent	WO 2004012614

#### Alerting Abstract US A1

NOVELTY - The **apparatus** has an elongate unit (130) with a proximal end and a distal end, where the distal end is adapted to be positioned within an anatomic void, and a **vibration device** (100) connected to the proximal end of the elongate unit. The **vibration device** creates a **vibration** at the distal end of the elongate unit, so that the media is mixed and/or compacted within the anatomic void.

DESCRIPTION - INDEPENDENT CLAIMS are also included for the following:

N. an apparatus for delivering a **media** to a target site within a bone structure

O. a method **for** delivering media to a **target** site within a bone structure.

USE - Used for compacting, liquefying and/or mixing a media e.g. bone cement to a void within a bone **structure**, an aneurysm, a vessel or other **body** cavity.

ADVANTAGE - The apparatus mobilizes the particles or granules that are **clustered** and became jammed or immovable in the channel, and facilitates movement of the solid particles or granules through the channel.

DESCRIPTION OF DRAWINGS - The drawing shows a side view of a compaction device.

22 Handle

100 Vibration device

128 Compaction device

130 Elongate unit

132 Distal tip